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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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19

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/202,359

Applicant(s)

Arad

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2001
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 1-7 and 9-11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 12-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d):
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) Interview Summary (PTO 413; Paper No(s): _____
- 16) Notice of Draftperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO 152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____ 20) Other _____

Pursuant to the directives of paper No. 16 (filed 2/20/00), claims 8 and 12-17 have been amended, and claims 18-19 added. Claims 1-19 remain pending, of which 1-7, 9-11 remain withdrawn from consideration. Claims 8 and 12-19 are examined in this Office action.

Applicants' arguments filed 2/20/00 have been considered and found persuasive in part. Most of the previously imposed rejections are withdrawn herewith. However, new grounds of rejection are now imposed.

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An abstract is required, and does not appear to be present.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The previously imposed enablement rejection is withdrawn, in view of the amendment. A new ground of rejection is imposed, however. The claims encompass a process in

which neither the time nor the conditions are effective to achieve the intended result. This ground of rejection can be overcome by incorporating the following phrase:

...for a time and under conditions effective to inhibit picornaviral replication. The

following claim language is suggested:

A method of inhibiting picornaviral replication in a subject that is infected with a picornavirus, said method comprising administering to said subject a compound of the formula ...

... for a time and under conditions effective to inhibit picornaviral replication.

*

Claims 8 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In at least one of the claims (claim 8), it is recited that substituent variables Y and Y' can be hydroxyl. It does not appear that there is support in the specification for this. Applicants should point to the page and line number where support may be found.

Claims 17 and 19 recite the following: "which includes the use of". Applicants should point to the page and line number where support may be found.

In claims 18 and 19, it is recited that Y and Y' cannot be hydrogen simultaneously. However, there does not appear to be support for this. It appears that applicants are

attempting to "carve out" a subgenus for exclusion, which is contrary to the principle conveyed in *In re Baird*.

✱

Claims 8 and 12-19 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are indefinite as to whether the compound is actually administered to the subject or not. If the compound is added to a test tube, is that sufficient? Claims 8, 12-16, 18 recite that an "effective amount" is administered. This renders the claims indefinite as to the intended purpose of the "effective amount". The claims are indefinite with respect to the process steps and endpoint. These ground of rejection can be overcome by requiring administration to the subject, by deleting "effective amount", and by incorporating the following phrase:

...for a time and under conditions effective to inhibit picornaviral replication.

The following claim language is suggested:

A method of inhibiting picornaviral replication in a subject that is infected with a picornavirus, said method comprising administering to said subject a compound of the formula ...

... for a time and under conditions effective to inhibit picornaviral replication.

- At least one of the claims (e.g., claim 8) recites that variable R1 can be a peptidomimetic "having substantially similar binding properties as the oligopeptide". This renders the claim indefinite. Which binding properties in particular?
- In claim 13, variables Y and Y' are defined. It is recited that they can be the following: -F -CN, - COOH.
However, the hyphen which precedes the carboxyl group should be adjacent to the carboxyl group, and on the same line as the carboxyl group. The same applies in claim 14.

- Claims 17 and 19 recite that the method "includes the use" of the recited compounds. This renders the claims indefinite as to the process steps.
- Each of claims 8 and 17 recite that Y and Y' can be keto, carbamido, sulfoxide or alkylsulfonyl sulfone. However, each of these functional groups must be bonded to two other groups; only one of these is accounted for. Accordingly, the claims are rendered indefinite. A ketone, for example, is a carbonyl group that is bonded to two other groups. In the case of, e.g., claim 8, what other group can the carbonyl be bonded to... an alkyl group, an alkaryl group, a heterocyclic group... what are the options? If descriptive support is lacking for any of these, it is suggested that the foregoing terms be eliminated from the claims.
- In claim 13, it is stated that "Z and Z' are hydroxyl...". Probably what is intended is to recite that *Z and Z' are hydroxyl...* If not, then Z' is undefined.
- Claims 8 and 18 permit Z' and R₁ to form a ring. The order of the definitions is first, a definition of variable R₁; this is followed by a definition of Z and Z', which is followed by a definition of Y and Y'. Only then is the following stated:

"or alternatively Z' and R₁ collectively form a ring..."

Instead, the phrase at issue ("or alternatively Z' and R₁ collectively form a ring...") should precede the definition of Y and Y'. Otherwise, the phrase at issue could mean that if Z' and R₁ collectively form a ring, then all of the remaining substituent variables can correspond to anything.

- In claim 15, the phrase "has the formula" appears to follow the structural formula, rather than preceding it.
- In claim 17, preceding the definition of variable "X", the term *wherein* should be present.

✱

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 18 are rejected under 35 U.S.C. §102(b) as being anticipated by Berger (USP 3,657,436).

As indicated previously, Berger teaches (col 2, line 7) that the compounds disclosed in col 1, line 34+ can be used to treat encephalo myocarditis virus. Since this is caused by a picornavirus, the claim is anticipated.

In imposing this rejection previously, applicants argued that the carbon at the 6-position of the phenyl ring was always hydrogen. However, this is not correct. As is evident from table I (col 2), a chlorine atom may be present at this position. In addition, there are two compounds listed which are derivatives of benzoxazine-4-one, one of which has a chlorine at the requisite position.

Thus, the claims are anticipated.

✱

Claims 8, 12, 14, 17-19 are rejected under 35 U.S.C. §102(b) as being anticipated by Baratz (USP 4,333,941).

Baratz teaches (col 3, line 7) inhibition of picornavirus. The compounds used are those of formula I (col 1, line 45+). Substituent variable R' (of the reference) can represent halogen. For example, there can be (col 5, line 51+) a chlorine atom *meta*- to the carbonyl

group.

The instant claims require that Y and Y' represent a substituent other than hydrogen; halogen is one possibility.

Thus, the claims are anticipated.

✱

Claim 8 and 18 are rejected under 35 U.S.C. §102(b) as being anticipated by Singh (*Tetrahedron Letters* **32**, 5279, 1991).


Singh teaches (p. 5280) the compound thysanone, which inhibits rhinovirus. This corresponds to applicants variables as follows:

Z = H
Y = OH
Y' = OH
R3 = H
Z' and R₁ form a ring

Thus, the claims are anticipated.

✱

No claim is allowed.


DAVID LUKTON
PATENT EXAMINER
GROUP 1800

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.